

FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Gastrointestinal Drugs Advisory Committee (GIDAC)
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm.
1503), Silver Spring, MD

January 12, 2011

Draft Agenda

The committee will discuss the safety and efficacy of new drug application (NDA) 022486, for Sollpura (liprotamase) Capsules, by Alnara Pharmaceuticals, for the proposed indication (use) in the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.

8:00 a.m.	Call to Order and Introduction of Committee	Jean-Pierre Raufman, M.D. (Chair) Gastrointestinal Drugs Advisory Committee
	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Official, GIDAC
	Opening Remarks/Introduction/Background	FDA
8:30 a.m.	Sponsor Presentations	Alnara Pharmaceuticals
10:00 a.m.	Clarifying Questions from the Committee to the Sponsor	
10:15 a.m.	Break	
10:30 a.m.	FDA Presentations	FDA
11:45 a.m.	Clarifying Questions from the Committee to the FDA	
12:00 pm	Lunch Break	
1:00 pm	Open Public Hearing (OPH)	
2:00 p.m.	Committee Discussion and Questions	
3:00 p.m.	Break	
3:15 p.m.	Continue Committee Discussion and Questions	
5:00 p.m.	Adjourn	